DR. BROWN: We actually used the distribution.

MR. CARSON: We used the distribution to map out what the cost would be based on that. So, that distribution, as he is saying, had Pennsylvania around 7 to 9 percent?

DR. BROWN: Yes.

MR. CARSON: Then others around 12 percent.

DR. BROWN: That is the mean.

MR. CARSON: And that was the mean. So, we used those numbers in factoring the costs. But, again, the costs of those positive environmentals are really attributed to the egg testing because that would be the follow-on additional costs if you had positives.

The other question which I sort of punted on was flies, and my badminton racket missed them all. So, I am going to ask Nancy to try and respond.

MS. BUFANO: There is a brief discussion of flies in the preamble to the rule, if you look

on page 56-835, as was published in the Federal Register. It references a paper by Olson and Hammock, "isolation of salmonella species from the house fly and the dung fly at cage layer houses." it was printed in the Journal of Food Protection. Basically, the paper showed that several salmonella species were found in house flies and dung flies that were collected at cage layer facilities. Those facilities had produced eggs that were implicated as the food vehicle in outbreaks of SE infection, and SE was isolated from 2 of the 15 pools of house flies from those facilities. It is reference number 49, back in the reference section of the proposed rule.

Stakeholder Public Statements

MR. CARSON: I believe those are two of the outstanding questions we didn't quite respond to earlier. Now I am going to open it up for comments. I realize that some of you, when you registered, may have indicated that you wanted to speak. I may not have received that. I only have three groups or three people who have formally

asked to speak. I am simply going to introduce them and after the third one speaks I will certainly open it up for additional people in the audience to have comments. So, I apologize if we have missed that you wanted to speak. The first is a series of speakers from the State of Pennsylvania, and starting off is Chris Pierce with the Pennsylvania Poultry Council.

MR. PIERCE: First of all, I want to say good morning and thank you for allowing me to share some comments this morning. My name is Chris Pierce and I am the Chairman of the PennAg Poultry Council. We are an association of poultry companies and farmers across the State of Pennsylvania. I would like to thank you that we can share these comments on the proposed egg safety rule.

Pennsylvania has the most intensely monitored *Salmonella enteritides* risk reduction program in the United States. We are the third largest egg production state in the country, supplying a majority of the eggs that are sold in

the Mid-Atlantic region for table consumption. So, food safety is taken very seriously by us. Pennsylvania's HASOP programs for eggs has led the way to food safety since the year 1997 and now stands at the forefront of national standards throughout the program that we call PEQAP, the Pennsylvania egg quality assurance program.

So, let me just take a brief minute to describe some of the highlights of our program. First of all, the PEQAP program is a voluntary program, developed by the egg industry and it is administered by the PennAg Poultry Council. We are a non-profit agricultural trade association. It utilizes risk-reducing management practices; notable environmental and egg testing, computerized database and, most importantly, third-party monitoring of all segments of the program by Pennsylvania's Department of Agriculture.

The certified Pennsylvania Animal Diagnostic Laboratory is at Penn State University, the University of Pennsylvania's New Bolton Center and the Department of Agriculture provide

laboratory testing of eggs and environmental samples. Annually, the egg industry invests over $1 million on implementation, promotion and public awareness.

The guidelines under the PEQAP cover egg production and ensure the commitment of the producer and processor to implement the best management and monitoring practices most likely to prevent SE contamination. Basic measures include continuous environmental testing of layers and poultry houses, buying only SE-negative chicks and utilizing an intensely monitored control program in cleaning and disinfecting between flocks. Any positive eggs, eggs that are found to contain *Salmonella enteritides* organism, are immediately removed from the table egg market and diverted to a pasteurizing facility.

In Pennsylvania we believe that the PEQAP program has accomplished its goal of reducing the risk of *Salmonella enteritides* in shell eggs. We request that FDA recognize the merits and strengths of the PEQAP program and, along with any other

state's program, to allow it to be accepted in its entirety or part of the final rule.

In addition to the numbers of the analysis of the program, other reviews of the program have recognized the merits of our protocols. According to the 15-member review team report prepared by the FDA, the Center for Disease Control and Prevention and USDA, dated January 18, 1997, it is stated that PEQAP can serve as a prototype for the egg industry in the development of the egg quality assurance programs and the industry should adopt quality assurance programs based on the interventions developed by the Pennsylvania pilot project and used by the Pennsylvania egg quality assurance program.

In final, we strongly hope that in the name of the real-world risk reduction efforts the high bar established by Pennsylvania would remain as an incentive for all eggs produced in the United States.

I do have a couple of other comments we would like to share from the PEQAP program. The

first would be Dr. Paul Patterson from Penn State University, then it would be Dr. Eric Gingrich from the University of Pennsylvania's New Bolton Center.

DR. PATTERSON: I wanted to respond to some of the questions that FDA had asked and maybe provide some helpful input. One question asked was about the requirement for pullets to be tested. Pullet requirements are needed as part of the program. We feel, through our experiences with PEQAP that manure swab testing of source pullet houses is useful. If pullet testing is not done, environmental testing is done immediately after placement in the destination house in Pennsylvania.

I would just like to reiterate that our early experiences in our HASOP approach to this program looked at all the critical control points and we identified pullet chicks, pullet houses, rodents and positive environments as risk factors, and pullets can be an issue, and we feel that they are important in the process. We test chick papers as one step and then again we test environmental samples of pullets. It is important that these

pullets don't go forward in the production scheme in the layer houses. So, it is an early opportunity in our mind.

Regarding mandatory biosecurity procedures, we recommend that biosecurity measures be implemented and appropriate ones should be used for reduction of all diseases, including diseases other than SE. But we recommend that any biosecurity recommendations be dictated by the state rather than maybe the federal government.

We have concerns about the fly issue, as maybe I had indicated earlier. We believe pest control is important for SE reduction, especially rodents, but I guess I am aware of that paper that you were talking about and I don't know that we can hang our hat on one study. We have done a lot of testing associated with PEQAP on a number of different issues, including flies, and we do find SE-positive flies on occasion but they don't necessarily correspond with SE-positive houses. I would just ask FDA to consider the ramifications of an SE-positive environment and positive flies, and

if you have the tools to test flies and then deliver risk reduction programs for those flies it would be a huge issue I think.

Regarding the C&D and wet washing of all positive houses, this is a tough issue because cleaning and disinfection in our own studies has demonstrated reduction in SE positivity in future testing but, on another note, I will just say that some of these houses come positive again as a result perhaps of the west washing. So, any time you have organic matter that is left behind and you hydrate this organic matter there is opportunity for those organisms to survive. So, in our own work, I would like maybe Dr. Gingrich to comment on this because we continue to research this topic.

DR. GINGRICH: Yes, I am Eric Gingrich, veterinarian with the University of Pennsylvania. We have done some preliminary work on a dry-cleaning project or program, so to speak, where we selected houses that had previously been wet washed and went environmentally positive or manure positive in the next cycle. We took those houses,

went through a program of requiring SE vaccination of the pullets, a thorough dry cleaning, fumigation with formaldehyde, and then we monitored those flocks afterwards. We had 7 of these houses, in the cycle after the dry cleaning program only 2 out of those 7 became positive after that. So, we have some evidence that it is working. We approved this dry cleaning program for our PEQAP program, and I am in the process of gathering more data on the outcomes of those flocks that have been used in this program. I don't have that data yet but I will have that for future comments.

DR. PATTERSON: Just another comment, these stacked cages with belts are expensive pieces of equipment and wet washing is very hard on them. The other challenge is taking care of wash water, and that can be an issue in the winter, and an issue with USDA and environmental regulations.

One final comment is that this is a very expensive procedure, to wet wash a house, and it may not always be in the best interest of food safety.

Regarding the 36-hour proposal for refrigeration, we believe 36 hours is realistic. When eggs are refrigerated we recommend that the requirement for this on farm refrigeration be at a temperature no greater than 55 degree Fahrenheit. We believe that gets at that sweating issue to some degree and the opportunity for thermal cracks. The reasons for this are that eggs are generally held in an on-farm cooler for a relatively short period of time. There is evidence that any low level SE would benefit from its natural abilities to impede salmonella growth and multiplication until the albumin begins to degrade. Even at room temperature, this may take several weeks. And, the cost involved in remodelling and operating a farm cooler to maintain 45 degrees would be vastly different than 55 degrees, through our experiences looking at many of these facilities, and may not show a cost-benefit ratio.

I would like to address the environmental testing at 45 weeks. We support environmental testing. I think it is a good idea, but recommend

adopting maybe more rigorous procedures because, by implementing this at that point in time, I would say two-thirds of the eggs from those hens have already been laid. Additionally, by testing multi-flocks at 20 weeks of age, or post 20 weeks post molt, again a majority of those eggs have already been laid and I question if you have done the public any good in testing those at those late times in the program.

Egg testing, 4 tests every 2 weeks--we concur with this procedure. Alternative lifetime egg testing scheme--we recommend allowing individual states to determine monthly versus quarterly egg testing for the life of a flock, to be determined by laboratory capacity. We think there are going to be some real issues in coping with the numbers of samples in different parts of the country.

Regarding drag swabs and alterative methods, requiring drag swabs in each manure row is what we do in Pennsylvania. If the manure pits are unsafe for entry alternative swabbing strategies

are available, and we particularly use swabbing of walkways, egg belts, manure belts and de-escalators on a case-by-case basis and this has worked well in those settings. I just urge you to think about stack houses in this situation too.

Monthly lifetime egg testing--recently PEQAP changed to quarterly egg testing to meet FDA's recommendation. This protocol seems to be well accepted by the program now by participants and laboratories since its implementation back early in 2004.

Regarding the testing, we recommend federal funding to state monitoring agencies and testing laboratories. That would be our choice in that matter.

Administrative proposal for one person per farm handles the paperwork and oversees compliance. What we are doing right now requires training of all participants but does not require a designated individual for signature of records. We actually have a question here, is an official third-party recordkeeper allowed? Is this what you are

considering? Maybe you would care to answer or maybe do that later, I don't know.

Regarding records, would it be possible to submit electronic versions of records with or without a signature? We don't do signatory pages now, just that they are available for inspection upon any time an authorized agent of our PEQAP program would arrive at the facility.

Comments regarding the requirement to turn in written SE prevention plans, we currently do not recommend a written prevention plan although we have a memorandum of understanding with the Pennsylvania Department of Agriculture for program participation.

FDA's annual inspection, we are doing twice a year inspections now. What about facilities that would be out of compliance? Have you considered that, how frequently they would be visited? Re-inspection guidelines, have those been outlined to revisit SE-positive farms and who would carry out the inspections? I think you would probably outline that to us as a designate of FDA.

Lastly, regarding C&D of a positive house, would there be follow-up made by FDA or agents of FDA on that question as well?

Just a couple more here, regarding the mandatory standards for high risk human populations, you were asking for comment. We suggest that the goal cannot be achieved through mandatory federal requirements at the retain level. We would recommend continuing on-farm efforts while continuing educational efforts at the retail and the consumer level.

Lastly, regarding the egg testing in Pennsylvania, no longer do we use 480 eggs. Actually, we use 1,000 eggs at this point as well.

One comment on page 87 and 88, you stated there would be state and local assistance for the program. I just have a little concern with that. If this regards inspections, regulating and enforcement, we would just recommend that having state or state designates do this and we would not recommend having local agents being involved. That might get a little messy across the country. I

think that concludes the comments we wanted to make.

MR. CARSON: One question I have for one of the speakers of Pennsylvania, you mentioned that your program is voluntary. Can you tell us what number of egg farm/poultry farms participate and what number do not participate in the Pennsylvania plan?

MR. PATTERSON: Yes, approximately that number is 85 percent. That is the number of farms. That doesn't, however, reflect the number of the eggs produced in Pennsylvania. The share of eggs under the PEQAP program is actually greater than that.

MR. CARSON: We are trying to have this transcripted so you need to speak into the microphone, please.

MR. PATTERSON: Again, the answer to that is 85 percent of the farms in Pennsylvania are on the program but that doesn't represent the numbers of eggs that are covered by the program and it is actually greater than is the percentage of the hens

and eggs in Pennsylvania.

MR. CARSON: Thank you. The next speaker is Rich Wood, from FACT.

MR. WOOD: I am Richard Wood. I am the Executive Director of Food Animal Concerns Trust, or FACT. With me is Steve Roach and, hopefully, he can speak better than I can right now.

FACT is a non-profit organization that advocates for better farming practices to improve the safety of meat, milk and eggs. Over the years we have worked primarily with the FDA on feed safety and animal drug issues, and the USDA on foodborne pathogen concerns. For the last 20 years FACT also worked with 14 smaller egg farms in Pennsylvania marketing eggs from uncaged hens to major grocery chains on the East Coast and, beginning in 1991 on these farms, we included a control program for *Salmonella enteritides*. Steve managed the SE control program on these farms. By the way, only one of these farms really had a flock of less than 3,000.

When this egg safety proposal was first

being fashioned we were a part of the discussions with the FDA, the egg industry, Center for Science in the Public Interest and the Coalition of Consumer Groups to arrive at an agreement with all parties on the basic tenets of an on-farm egg safety plan, and we thank you for the opportunity to make brief comments today and to submit detailed written comments to the docket. Since we are based in Chicago, we will also be there and provide more detailed comments at that time.

We believe the proposed rule properly acknowledges that *Salmonella enteritides* continues to be a serious human health problem and that an intervention, focused on the farm, is required. Having worked for years in support of foodborne pathogen control, FACT applauds the FDA for anchoring this proposal in an assessment that accepts and understands the risks of *Salmonella enteritides* contamination, placing the first response within the farm-gate and the farm-table continuum.

In the past, as we all know, consumer

groups often responded to this kind of data from the CDC by blaming egg farmers. Egg farmers would often respond to the data by getting defensive and pointing at the retail establishments, and nothing got done, at least at the federal level. In my view, even though there were certainly elements of political gamesmanship going on, what really changed the climate was that four years ago the consumer groups, the egg industry and the FDA, in the midst of all of our own organizational goals, identified, expressed and shared one common goal and that is food safety. Once we acknowledged that we began to move forward. This common goal allowed us all to sit down around one table and work out the basic elements of a proposal.

In our view at FACT, today's proposed rule does express the agreement reached four years ago. It provides for one environmental test per laying cycle to verify the effectiveness of the egg producers' SE reduction plan, followed by egg testing and diversion when there is a positive. Environmental testing, as we see it, is a central

and important provision of an SE verification program, and environmental tests provide an accurate picture of whether or not the flock is contaminated. Infected eggs, of course, do not produce contaminated eggs all the time. Furthermore, not all hens in a flock are infected by SE at the same time.

While FACT SE protocol on our farms hat we worked in Pennsylvania diverted all the eggs from the house when an environmental positive was confirmed, as we know, the Pennsylvania the egg quality assurance program has demonstrated that conducting egg tests after a positive environmental is an effective protocol. We support this provision in the proposed rule and are certainly glad that PEQAP is helping to inform the development of this proposal as well.

Cleaning and disinfecting a house that is positive is also a critical component of this SE plan. As a matter of fact, after this plan is implemented it might be helpful to get additional data to determine whether or not it is important to

test a previously positive house after it has been disinfected. The proposed rule cites a study that shows that no house was positive after wet cleaning. Still, we head an example or a concern that that may not always be true. Our experience at FACT and in working with our farms demonstrated the need for this step. It could be an unfortunate setup for a farmer or for an egg producer to have placed a new flock in a previously contaminated house that, although cleaned and disinfected, still contained a positive SE environment. Egg producers themselves may want to take this testing step whether or not it is a part of the rule.

The protocol must not only verify the effectiveness of the producer's SE reduction plan, it must also protect the public from *Salmonella enteritides* infection. The test must take place early enough in the laying cycle so that if the eggs are positive there will be time to divert the eggs to pasteurization. We found on our farms that in the rare instances where we had an SE-positive environmental sample it was more likely to appear

40-45 weeks rather than earlier. FACT supports the FDA time frame for the first laying cycle but, certainly, we would welcome and hope that the FDA would welcome the perspectives of others and the data from others that might indicate a change when actually that one test in that laying cycle might take place.

We also support an environmental test following a molt if that is the farm's procedure, although for us forced molting is a practice that we would like to see ended altogether. But we encourage the FDA and all stakeholders to review the current draft--I am not suppose to say the other agency, right?--but the USDA risk assessment that I think found that SE is more likely to be present closer to molt than at 20 weeks--as you move further out the likelihood of SE to be there drops, which means that there is a likelihood of contaminated eggs going to the marketplace if the testing is later in that second laying cycle. So, perhaps an adjustment needs to be made.

Another strength of this plan is that it

provides for a uniform nationwide verification of the effectiveness of on-farm controls. It does create a level playing field for almost all egg producers, and creates a level playing field of expectations for consumers. Currently, as we all know, several states have quality assurance programs with varying requirements, as does the egg industry, but participation is voluntary and that level of participation varies from program to program and state to state. We see the federal rule as the bottom line that then can be exceeded by state programs for, as consumers, we do want to know that across the nation, wherever we buy our eggs, the farmer must provide the same level of SE controls--that is, unless the farm has less than 3,000 birds and we are currently surveying the small farms that we work with to discuss how they might be involved in this plan. I think that is something that needs to be taken a look at. The $40 million figure, the price tag that you placed on that assumed, I believe, that it would be the same level of administrative and inspection costs

as on the larger farms and that may not necessarily be the case if there can be some kind of modified involvement for those farms.

Finally, the FDA must make certain that once the rule is finalized it is fully implemented and enforced, including the inspection of farm records for compliance. When human health is at stake we can ill afford an unfunded and poorly implemented program. We encourage the FDA to explore every option available to provide for the complete implementation of this program and full enforcement, once in place.

The proposed egg safety plan is part of the continuum of food safety that truly begins on the farm, and we commend the FDA for placing the initiating point for this plan where the concern begins, on the farm.

We have a list of other concerns that Steve Roach can now address if you would like. Thank you very much.

MR. ROACH: I am Steve Roach, and I am the Food Safety Program Manager for FACT. I am kind of

looking at my list and me and Rich seem to have overlapped a little bit so, hopefully, I won't repeat what he said too much.

As Rich noted, my current work focus is on promoting appropriate pre-harvest controls to improve the safety of meat, milk and eggs. I also led FACT's research project on *Salmonella enteritides* on the cage-free lane farms participating in our nest/egg program. Farms participating in nest/eggs are required to follow a salmonella control program stipulated by FACT. We were in Pennsylvania and there was a little bit of a variation between our program and what PEQAP was doing but we tried to be fairly consistent, but we felt that we developed some different protocols because of the uncaged nature of the farms we work with.

The nest/egg salmonella program included many of the provisions of the proposed rule. Our program included the requirement that chick come from MPIP SE-monitored breeder flocks; extensive environmental sampling with diversion of eggs in

rare incidents of a positive; required by our security provisions vaccination, sampling of feed and water and refrigeration of eggs on farm.

One of the important aspects of our SE control was the purchase of chicks from MPIP SE-monitored breeder flocks. We feel this is a very important step in the proposed rule because the ability of SE to colonize eggs and risk of vertical transmission of SE can be best addressed by strict control and monitoring of breeder flocks.

We also require wet cleanout and disinfection, and FACT, you know, is aware of the controversy over whether wet cleanout is a benefit or harm. We do support cleaning out between flocks. You know, the proposal only requires that only for the ones that are positive and maybe that is a prudent thing but, you know, farmers should consider cleaning out more frequently. Also, what we feel strongly is that if farms do use wet cleanout, and maybe this is obvious, there needs to be sufficient down-time after the cleanout when it is wet to make sure you actually get it dry for a

period of time before you put the hens back in. I mean, that seemed to be the case in ours.

We also require testing the flock after a cleanout. I am not sure whether that should be mandated but it is a good idea because we had, after cleanout, after having a wet cleanout and dry, we require all our farmers to resample and there were occasions where we would find SE again, and we require the farmer to go back and clean out again. Again, that is something to think about. How do you address that? How do you know whether your cleanout was good enough? And, one way to do it would be an environmental sample.

In the proposed rule FDA asked whether additional recordkeeping measures are necessary. From our experience with nest/eggs, FACT believes that it would be difficult to create and implement an SE control plan without having it written down. Because of this, we support the farm having a written SE prevention plan. Similarly, we find it highly unlikely that an effective rodent control plan could be implemented without recordkeeping.

The flies--again, we are not sure how much of a factor that is. That might be something where we would agree with PEQAP. I think that needs to be examined. But if flies were to be used as an indicator of the sanitation controls on the farm, then you would probably want to keep records to see how that is changing over time. So, we have some trouble with seeing how you can have certain control programs where you aren't keeping records. It is just part of the control program, that you would keep your records when you did your rodent controls and what your rodent indices were, and if they are changing over time then you could respond to it.

In the FACT nest/egg program, as Rich noted, forced molting was not allowed because of concerns about its impact on hen welfare. While we accept that this is not the appropriate venue to discuss welfare concerns, we do believe that molting must be considered when considering steps to control SE, and FACT supports the provision and the role for environmental sampling after a molt.

We feel that the timing of the sampling perhaps should be adjusted based on the recently completed USDA SE risk assessment that found an elevated SE risk in the first 20 weeks after molt. In the proposed rule environmental sampling is required at approximately 20 weeks, and that is at the end of the period of elevated risk identified by the USDA.

The proposed rule justifies having the post-molt sampling at 20 weeks because this time is equivalent to the time period when layers are 40-45 weeks of age and in an initial egg cycle. The 40-45 week range was set because of evidence showing that this was a higher risk period for the first cycle. So, if the evidence is as suggested by USDA recent risk assessment that risk is higher before then, then maybe that time period would need to be adjusted to earlier.

FACT also has a concern with the definition of poultry house in the proposed rule. The current definition allows for a single building to be considered multiple houses as long as separate houses have walls between them where a

person can't move back and forth between the two houses. FACT is concerned because we believe there is evidence that SE could be transferred between houses so defined on feathers moving through the air. This could be a particular problem with multiple age groups where different houses would share air space. Again, we will look at this more in our written comments but I think it is something to be considered.

There is a proposal that possibly you could use static ways to test SE in the air. So, you know, if you can actually measure SE in the air, then it suggests that maybe you do need to be concerned about shared air space, especially if you have multiple ages of hens in different houses. And, that is something we are concerned about just as a definition of what actually is a poultry house. I just think more thought needs to be given to that.

Finally, FACT would like to acknowledge that diverting eggs in cases where SE is found can be very costly. From our understanding, the costs

are more from diversion of eggs, the loss value of the eggs, than from the actual testing itself. Maybe our ideas are biased because we didn't actually test the eggs so we didn't have those costs; we automatically went to the cost of diverting eggs. But the value of eggs when we had to divert them was--you know, it wasn't meeting the cost of production.

In the nest/eggs SE program we diverted whenever we found SE-positive environmental samples. We also ended up diverting eggs to breakers because of market reasons. Whenever we had to divert eggs it put the financial strain on the egg marketing business, and this is one of the reasons FACT supports a national regulation that evens the playing field between all egg producers. FACT also believes that some producers may find that it is prudent to take further steps behind those requirements in the proposed rule to reduce this financial risk.

We would like to note that sampling doesn't reduce the risk of anything but it might

incentivate farmers to actually take the steps the steps that would reduce the risk.

Finally, I would like to conclude by thanking the FDA for the important work it has done in creating this proposed rule. As Richard Wood noted, this rule reflects the common ground reached in consultation with a wide variety of stakeholders, both consumers and industry included.

We will be submitting written comments and we will also be submitting some further oral comments at the Chicago meeting that develop further the points that we discussed above. We hope the FDA will promptly review comments and that we will soon have the final rule. And, I think getting out the final rule is our highest goal because then we can start having some of the public health benefits. Thank you.

MR. CARSON: Thank you. The next speaker, Howard Maguire, United Egg Producers.

MR. MAGUIRE: First, thank you for the opportunity to comment on your egg safety rule this morning. I am Howard Maguire, representing United

Egg Producers. United Egg Producers members represent 90 percent of the shell eggs that are produced in the United States.

Egg farmers are dedicated to provide a safe product to our customers. UEP designed a five-star program several years ago. This quality assurance program has been used by producers across the nation, and it has also been formally adopted by several states. Our members also take part in several other quality assurance programs that were designed by the states, and you heard several speakers this morning talk about the Pennsylvania Egg Quality Assurance Program.

These egg quality assurance programs have made a real difference. As referenced by Ms. Bufano earlier this morning, the Centers for Disease Control and Prevention published a study of state and industry quality assurance plans which concluded--and I will quote here, that egg quality assurance programs probably played a major role in reducing *Salmonella enteritides* illness in the United States.

Even one egg-related illness though is too many. However, we should not ignore the progress that has been made, and I was going to cite some statistics here but I think Dr. Braden did a lot better job of that this morning already to show how, over several years, illness have gone down, and again in 2001 and 2002 compared to 2000.

When FDA first began to discuss its egg safety action plan some five years ago, our producers felt that the original form of the plan was too expensive, overly burdensome and unnecessarily restrictive. However, the agency modified its original concepts to make them more practical and then FDA published the current thinking documents, that you are all familiar with, in 2000 that responded to many of our concerns and those of others, for example, by requiring diversion only when you have a positive egg test.

We responded positively to the current thinking documents four years ago; we will honor that commitment today. The proposed rule in its broad outlines is faithful to the 2000 documents.

We applaud FDA in that regard. That does not mean, however, that the proposed rule is perfect. Our members, as well as scientific experts, have expressed several concerns. These concerns to not call into question the role of quality assurance programs. The evidence, as I referenced, is overwhelming that these measures can help produce a safer product, but this proposed rule does raise some questions that need to be addressed.

I would like to start with two broad thoughts about how the rule will be implemented, and then use the remainder of my allowed time to comment on a few specific and technical issues.

First, the agency needs to make certain that this rule does not weaken, compromise or duplicate existing state and industry egg quality assurance programs, for example, the Pennsylvania program. At least 15 states have official egg quality assurance programs. The CDC, as I mentioned earlier, found a strong relationship between adoption of these plans and improvements in SE rates. With this proven track record, we would

suggest a regime whereby FDA would review existing plans to determine whether they are equivalent to FDA's own requirements. Compliance with the recognized plan would satisfy the producers' requirements under the proposed rule. An approach like this would reward success; honor federalism; and minimize new demands on FDA's own resources.

Secondly, while FDA and others have noted a potential partnership and other federal agencies, the rule itself is a bit unclear in this regard and we would suggest that FDA adopt a proposal that our organization has consistently made since the egg safety action plan was fist announced. We believe that FDA should minimize duplicative regulation by utilizing federal and state agencies that already regulate the egg industry to carry out inspection and enforcement of this rule. The most obvious model is the Agricultural Marketing Service at USDA. AMS inspects all egg packing facilities four times a year under the Egg Products Inspection Act. In many cases, AMS uses state agencies for this program, often the same state agencies that

are also administering the state egg quality assurance programs. It seems to be a natural fit.

By using state and federal personnel who are already regulating the industry, FDA will avoid the need to hire additional personnel of its own. Frankly, we are not certain that any other arrangement, in light of today's tight budgetary constraints, will permit FDA to fulfill the annual inspection goal as laid out in the proposal.

Now to the technical issues, first, can existing laboratories handle the big increase in testing that will result from this rule? Academic experts we have talked with aren't sure, and partly because the rule hadn't yet specified which laboratories can run the tests.

We would also urge the agency to reconsider the sample size for egg testing. While 50 analyses of eggs may be statistically valid for a 100,000 bird house, that may be excessive and certainly very expensive for a house of 10,000 birds.

Second, as Dr. Patterson talked earlier,

is 36 hours the right time for the rule's refrigeration requirement? Eggs going to the table market must be washed and when they are refrigerated beforehand the temperature change during washing will be much greater than normal if the eggs are refrigerated. The result is known to be more checks or hairline cracks, which in itself is a food safety problem and not healthful. We believe the agency should consider a longer period than 36 hours, not radically longer but something longer.

Third, shouldn't there be positive incentives for producers that use vaccination, not as a substitute for other quality assurance measures but as an adjunct to those measures? Vaccination has demonstrated success not only here but also in the United Kingdom where it is an integral part of that country's quality assurance program.

Fourth, to follow-up on what some other speakers said, will wet cleaning really be helpful in reducing SE? FDA does acknowledge the

conflicting science on this point, and many of the experts we consulted are alarmed by the wet cleaning requirement, fearing that that will result in an SE bloom in the house.

Another issue here is geography. It is almost physically impossible to wet clean a house in some of our northern states in the wintertime.

Fifth, are all the biosecurity measures outlined in the proposed rule necessary? The industry recognizes the importance of biosecurity measures not only for food safety but also for flock health, for example, avian influenza and exotic New Castle disease. However, several scientists that we have spoken to and producers are concerned that some of the measures suggested in the proposed rule are impractical and may have little positive impact on biosecurity.

Last, we urge the agency to consider indemnification for cost incurred with egg diversion when a positive egg test is encountered. There is certainly precedent for this at USDA and legislation that is directed toward the control of

animal disease.

To finish up here, I would be dishonest if I said there is universal agreement with this proposed rule within the egg industry. There is not. But we have offered these suggestions for improvements in the spirit of constructive cooperation since all of us share the same goal, and that is to ensure the safety--the same goal as producers, consumers and public officials. Thank you.

MR. CARSON: I would like to now open up for additional comments to be made. If you just raise your hand. Yes, ma'am?

MS. LOAF: Hi. I am Brenda Loaf, from Penn State. If you can take another speaker about the PEQAP program, I want to talk about the laboratory capacity. I am a bacteriologist there. In 2001 the bacteriology group at Penn State and also at New Bolton figured the cost per sample. For a negative environmental sample it was $5.83; for a positive environmental sample it was $13.87--I can't quite see this even with bifocals.

The protocol that we use, we go into tetrathionate broth, which is selective pre-enrichment, and then we go onto two agar plates to grow the organism. We pick a total of five colonies from these agar plates. The protocol that is outlined in the proposed rule is to go into buffer peptone water, which is non-selective enrichment, then to go into tetrathionate and RV, both selective enrichments, and from both of those selective enrichments to go onto three different agar plates, and from each one of those agar plates to pick a total of five colonies.

So, just consider, please, the difference in both the laboratory capacity, which has been mentioned which is a really the issue, and the cost. Thank you.

MR. CARSON: Other additional comments? If not, thank you. As we mentioned, the comment period closes on December 21, 2004 and we encourage you to submit comments to the dockets. We will be holding two additional public meetings, one in Chicago and one in Los Angeles. Again, our purpose

there is the same as here, to clarify the rule and to promote comments to this rule.

We have heard many good comments today. We will certainly take those into account. But, again, it would help us as people have referred to, their experiences concerning *Salmonella enteritides* in poultry houses. If you can also convey to us additional data that we may not have considered so that we can have that as a basis for your comments, we would certainly appreciate that. So, thank you all very much.

[Whereupon, at 12:25 p.m., the proceedings were adjourned.]

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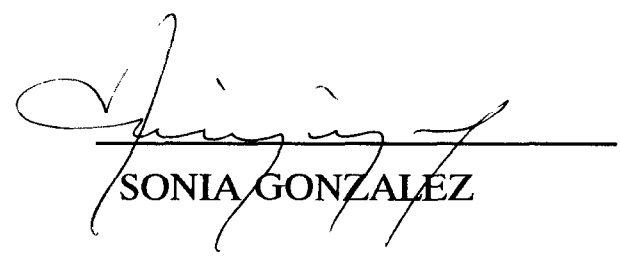
CERTIFICATE

I, **SONIA GONZALEZ**, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



SONIA GONZALEZ

Correction Sheet for the October 28, 2004, downlink transcript

The following changes in the transcript are submitted.

Page 1, line: 16
Correct: ENTERIDITIS

Page 2, line: 22
Correct: OFFICE OF PLANT AND DAIRY FOODS

Page 3, line: 22
Correct: PUBLIC THAT OBTAINS EGGS THAT DO NOT COME

Page 7, line: 3
Correct: *ENTERIDITIS*

Page 8, line: 7
Correct: USDA AGRICULTURAL MARKETING SERVICE (AMS)

Page 9, line: 20
Correct: ENTERIDITIS-CONTAMINATED

Page 10, line: 16
Correct: ENTERIDITIS

Page 14, lines: 12
Correct: CHAMPAGNE

Page 14, line: 21
Correct: CHAMPAGNE

Page 15, line: 8
Correct: CHAMPAGNE

Page 15, line: 9
Correct: CHAMPAGNE

Page 20, line: 8
Correct: ENTERIDITIS

Page 23, line: 15
Correct: ENTERIDITIS

Page 23, line: 17
Correct: SEROTYPE HEIDELBERG

Page 23, line: 17
Correct: ENTERIDITIS

Page 24, line: 4
Correct: ENTERIDITIS

Page 24, line: 8
Correct: ENTERIDITIS

Page 24, line: 17
Correct: ENTERIDITIS

Page 25, line: 8
Correct: ENTERIDITIS

Page 26, line: 20
Correct: ENTERIDITIS

Page 27, line: 9
Correct: ENTERIDITIS

Page 27, line: 18
Correct: BARNETT: THE QATAIR IS YOUR NAME FOR

Page 28, line: 21
Correct: ENTERIDITIS

Page 29, line: 21
Correct: ENTERIDITIS

Page 30, line: 11
Correct: ENTERIDITIS

Page 31, line: 4
Correct: ENTERIDITIS

Page 31, line: 17
Correct: SCHWANN'S

Page 31, line: 22
Correct: ENTERIDITIS

Page 33, line: 19
Correct: AND A CATCH-ALL CATEGORY

Page 34, line: 14
Correct: ENTERIDITIS

Page 36, line: 10
Correct: ENTERIDITIS

Page 39, line: 10
Correct: ENTERIDITIS

Page 39, line: 15
Correct: ENTERIDITIS

Page 40, line: 3
Correct: ENTERIDITIS

Page 40, line: 9
Correct: ENTERIDITIS

Page 44, line: 3
Correct: THAT IS ALSO

Page 46, line: 2
Correct: ENTERIDITIS

Page 47, line: 7
Correct: WITHIN HOUSES AND DEBRIS AND VEGETATION

Page 48, line: 9
Correct: ENVIRONMENTAL

Page 48, line: 15
Correct: BEGIN EGG TESTING WITHIN 24 HOURS

Page 50, line: 9
Correct: IF IT IS NEGATIVE WAIT 2 WEEKS AND THEN CONDUCT A

Page 50, line: 11
Correct: IF IT IS NEGATIVE WAIT ANOTHER 2 WEEKS;

Page 50, line: 13
Correct: IF IT IS NEGATIVE WAIT ANOTHER 2 WEEKS,

Page 50, line: 17
Correct: IF IT IS NEGATIVE

Page 50, line: 18
Correct: IN OTHER WORDS YOU'RE AT YOUR SECOND OR THIRD

Page 52, line: 13
Correct: THE PROPOSED RULE REQUIRES THE FOLLOWING:

Page 53, line: 10
Correct: USING AN ALLIANCE SIMILAR TO WHAT WE HAVE DONE FOR JUICE HACCP AND SEAFOOD HACCP

Page 54, line: 14
Correct: PEST CONTROL/BIOSECURITY;

Page 57, line: 18
Correct: FOLLOWING:

Page 62, line 4
Correct: FARMS WITH LESS THAN

Page 65, line: 12
Correct: MS. SMITH-DEWALL

Page 65, line: 13
Correct: MS. SMITH-DEWALL

Page 67, line: 9
Correct: MS. SMITH-DEWALL

Page 67, line: 16
Correct: THEN, YOU HAVE TO START OVER AGAIN IF YOU WANT TO

Page 67, line: 17
Correct: GET BACK INTO TABLE PRODUCTION OR YOU CAN JUST

Page 67, line: 18
Correct: CONTINUE TO DIVERT AND NOT DO ANY MORE TESTING. IF YOU WANT TO

Page 68, line: 7
Correct: MS. SMITH-DEWALL

Page 68, line: 13
Correct: MS. SMITH-DEWALL

Page 70, line: 5

Correct: MS. SMITH-DEWALL

Page 71, line: 15
Correct: MS. SMITH-DEWALL

Page 71, line: 17
Correct: ENTERIDITIS

Page 72, line: 9
Correct: MS. SMITH-DEWALL

Page 72, line: 20
Correct: HACCP AND HACCP

Page 72, line: 22
Correct: HACCP

Page 74, line: 10
Correct: BUT,

Page 76, line: 5
Correct: POPULATION

Page 79, line: 15
Correct: MS. SMITH-DEWALL

Page 80, line: 18
Correct: MS. SMITH-DEWALL

Page 87, line: 14
Correct: AGRICULTURAL MARKETING SERVICE

Page 88, line: 7
Correct: ESTABLISHED.

Page 101, line: 16
Correct: THAT TESTED POSITIVE FOR ENVIRONMENTAL S.E.

Page 102, line: 21
Correct: 56835

Page 103, line: 2
Correct: ISOLATION

Page 103, line: 3
Correct: It

Page 104, line: 22
Correct: PENNSYLVANIA'S HACCP PROGRAMS

Page 106, line: 12
Correct: ENTERIDITIS

Page 106, line: 17
Correct: ENTERIDITIS

Page 108, line: 12
Correct: ENTERIDITIS

Page 112, line: 4
Correct: DEGREES

Page 112, line: 12
Correct: ALBUMEN

Page 116, line: 8
Correct: RETAIL LEVEL.

Page 118, line: 17
Correct: ENTERIDITIS

Page 119, line: 11
Correct: ENTERIDITIS

Page 119, line: 17
Correct: ENTERIDITIS

Page 120, line: 11
Correct: ONCE WE ACKNOWLEDGED THAT, WE BEGAN TO MOVE FORWARD

Page 121, line: 6
Correct: FARMS THAT WE

Page 121, line: 9
Correct: AS WE KNOW, THE PENNSYLVANIA EGG QUALITY

Page 122, line: 16
Correct: ENTERIDITIS

Page 126, line: 10
Correct: ENTERIDITIS

Page 126, line: 22
Correct: CHICKS

Page 127, line: 2
Correct: NPIP SE MONITORED BREEDER, FLOCKS; EXTENSIVE

Page 127, line: 8
Correct: CONTROL WAS THE PURCHASE OF CHICKS FROM NPIP

Page 133, line: 5
Correct: FARMERS TO ACTUALLY TAKE THE STEPS THAT

Page 135, line: 5
Correct: ENTERIDITIS

Page 135, line: 11
Correct: ILLINESSES

Page 143, line: 14
Correct: ENTERIDITIS

*** Note: These lines are intentionally left blank.**

DATE: **December 29, 2004**

SUBJECT: Egg Safety Proposed Rules Public Comments & Meetings

FROM: Marion V. Allen
Food Safety and Security Staff (HFS-32)

TO: Docket Nos. 1996P-0418, 1997P-0197, 1998P-0203, and 2000N-0504]
RIN 0910-AC14

Please find enclosed the following documents related to the Egg Safety Proposed Rule:

- October 28, 2004 – Public Meeting Transcript (College Park, MD) w/ errata sheet
- FINAL Registration Listing for 10-28-04
- FINAL Registration Listing for 11-09-04
- FINAL Registration Listing for 11-16-04
- PRE-TAPE w/Dr. Lester Crawford that was presented at the Chicago & LA meetings
- Presentations CD
- CD w/Final Registrants & 10/28 Transcript and errata sheet